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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/506,959

09/14/2005

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EXAMINER

LANDRY II, GERALD ERNEST

ART UNIT

PAPER NUMBER

3763

MAIL DATE

DELIVERY MODE

07/31/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/506,959	<b>Applicant(s)</b> ANDERSON ET AL.	
	<b>Examiner</b> GERALD LANDRY II	<b>Art Unit</b> 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 14 September 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-56 is/are pending in the application.
- 4a) Of the above claim(s) 1-30 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 31-56 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 07 September 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>09/14/2005, 03/24/2009</u> .                                  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Drawings***

1. New corrected drawings in compliance with 37 CFR 1.121(d) are required in this application because certain figures remain unclear, namely figures 5-8, 9B, and 12-15. Applicant is advised to employ the services of a competent patent draftsman outside the Office, as the U.S. Patent and Trademark Office no longer prepares new drawings. The corrected drawings are required in reply to the Office action to avoid abandonment of the application. The requirement for corrected drawings will not be held in abeyance.

### ***Specification***

2. The disclosure is objected to because of the following informalities: page 1, lines 17-18 state "one or more part".

Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claim 50 recites the limitation "second casing component" in line 1. There is insufficient antecedent basis for this limitation in the claim.

### ***Claim Rejections - 35 USC § 102***

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 31-56 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,447,475 to Castellano.

Regarding claims 31-56, Castellano teaches a casing; a cartridge containing a medicament and an orifice at one end; a drive mechanism **(5029)** which upon actuation applies force to the medicament, forcing the medicament out of the orifice and through the patient's skin; a trigger mechanism **(5034, 5037)** which actuates the drive mechanism; a safety mechanism **(5026)** which, in a first configuration, prevents the trigger mechanism from actuating the drive mechanism and in a second configuration allows trigger mechanism to actuate the drive mechanism, wherein the casing encloses injector device components and incorporates an actuator mechanism which moves the safety mechanism from its first configuration into its second configuration **(column 20 line 62 – column 23 line 28)**; wherein the actuator mechanism comprises a portion extending outside of the casing which portion is accessible to a user and which when the portion is moved by the user the movement brings the safety mechanism into its second configuration **(refer to marked-up figures below and columns 20-23)**; wherein the safety mechanism in its first configuration prevents the trigger mechanism from moving **(column 23 lines 21-24)**; wherein the actuator mechanism has a structure selected from the group consisting of a button **(refer to marked-up figures below)**, a tongue **(refer to marked-up figures below)** and a lever; wherein the actuator mechanism is comprised of a component **(5080)**

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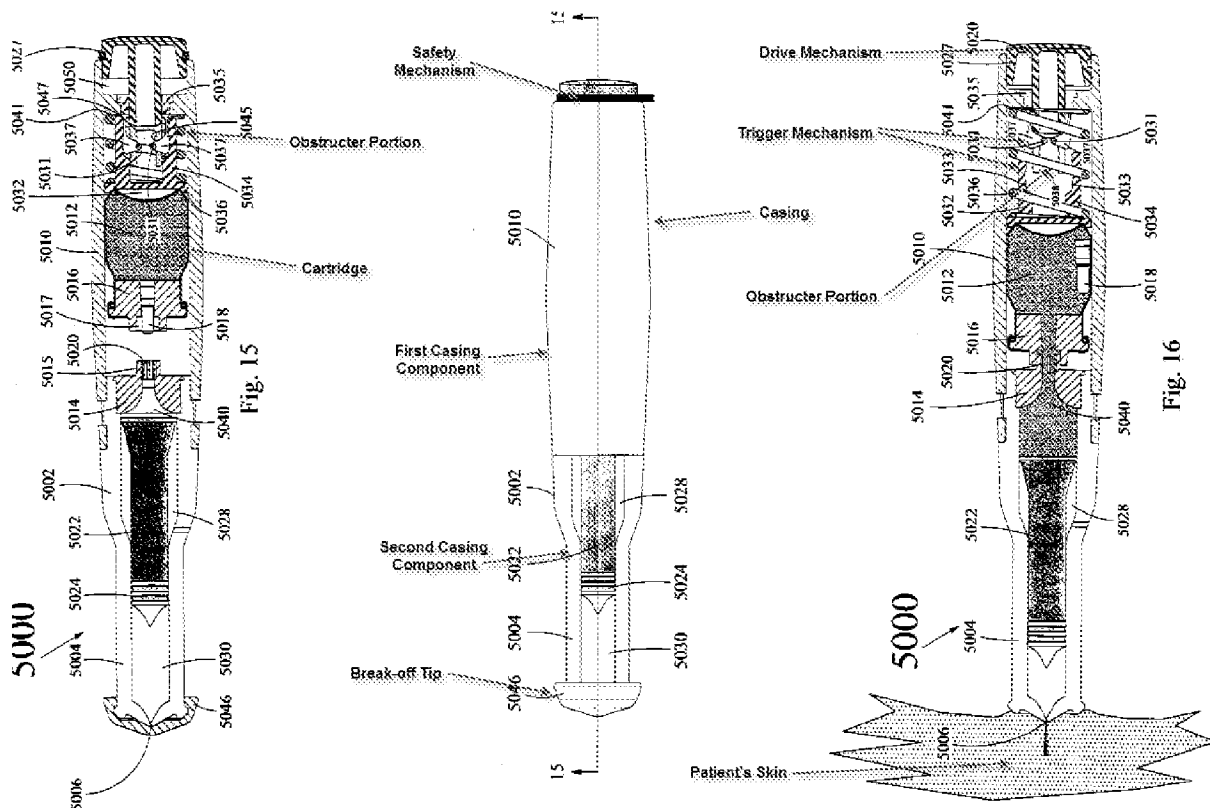
which applies a pulling force to the safety mechanism to pull the safety mechanism from its first configuration into its second configuration (**column 23 lines 24-28; note: “a” pulling force**); further comprising: a retaining mechanism (**5010**) which retains the safety mechanism of an enclosed injection device in its second configuration after the safety mechanism has been brought into its second configuration (**column 23 lines 21-24 denotes capability**); wherein the safety mechanism comprises an obstructer portion (**spring; column 23**) which in the first configuration obstructs, and in the second configuration allows, movement of the trigger mechanism (**column 23**); wherein the safety mechanism comprises a collar (**5026**) shaped to surround a portion of the injection device, the collar is moveable from its first collar configuration into its second collar configuration in a direction generally perpendicular to a direction in which the medicament exits the orifice, the collar comprising an obstructer portion (**column 23**); wherein the trigger mechanism is comprised of two moveable upper and lower sleeve portions which on relative movement allow the drive mechanism to act, and the safety mechanism comprises an obstructer portion (**see above**) which in its first configuration obstructs, and in its second configuration allows, the relative movement of the sleeve portions (**refer to marked-up figures below**); wherein the safety mechanism comprises an obstructer portion which is brought from its first configuration to its second configuration by a movement of the obstructer portion in a direction perpendicular to a direction of relative movement of the two sleeve portions (**i.e. a spring, column 23 (also note that it is possible for the spring to expand radially)**); a casing which partially encloses a needleless injection device (**refer to marked-up figures below**); a drive mechanism which forces medicament out of the orifice and through the patient's skin (**refer to marked-up figures below**); a break-off tip (**5046**) which closes the

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cartridge orifice prior to being broken off; wherein the casing provides for a sequential operation of the needleless injection device (**refer to marked-up figures below**); wherein the sequential operation provides for (a) breaking off the break-off tip; and (b) placing the safety mechanism in the second position (**refer to marked-up figures below and column 23**); wherein breaking off the break-off tip exposes an actuator for the safety mechanism (**allows for actuation thus exposing the actuator**); wherein the casing comprises moveable first and second casing components, a first casing component adapted to hold the injection device, and a second casing component adapted to bear upon the break-off tip as a result of relative motion of the first and second components to apply a force thereto causing the break-off tip to break off from an injection device enclosed within the casing (**capability shown in marked-up figures below**); wherein the first casing component is elongated with an opening at a first end (**refer to marked-up figures below**); wherein the first casing component is elongated along a longitudinal axis, and wherein the second casing component is designed to apply a rotary motion relative to the first portion so as to bear on the break-off tip of a container held by the first casing portion, and to apply a twisting shearing force to the frangible joint between the break-off tip and the container (**capability shown in the marked-up figures below**); wherein the rotary motion is chosen from: transverse to the longitudinal axis; perpendicular to the longitudinal axis; coaxial with the longitudinal axis; about a rotation axis parallel to but non-coaxial with the longitudinal axis; about a rotation axis at a non-zero angle to the longitudinal axis (**this can be accomplished by twisting the second casing component**); wherein the rotary motion is about a rotation axis at a non-zero angle to the longitudinal axis (**capability shown in the marked-up figures below**); wherein the second casing component comprises a cover portion (**5046**) over the actuator for the

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safety mechanism which prevents operation of the actuator for the safety mechanism until the cover portion is removed; wherein the drive mechanism comprises a compressed gas cylinder (**abstract; 5012**); wherein the casing comprises a first casing sub-part and a second casing sub-part which fit together by a method chosen from, a tight friction fit, and a snap-fit fit (**capability shown in marked-up figures below**).



7. Claims 31-56 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent Pub. No. 2001/0031945 to Haar et al.

Regarding claims 31-56, Haar teaches a casing (**46**); a cartridge (**11**) containing a medicament and an orifice at one end; a drive mechanism (**48**) which upon actuation applies force to the medicament, forcing the medicament out of the orifice and through the patient's skin;

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a trigger mechanism **(36)** which actuates the drive mechanism; a safety mechanism **(39)** which, in a first configuration, prevents the trigger mechanism from actuating the drive mechanism and in a second configuration allows trigger mechanism to actuate the drive mechanism **(figure 4 to figure 5)**, wherein the casing encloses injector device components and incorporates an actuator mechanism **(outside of casing 46)** which moves the safety mechanism from its first configuration into its second configuration **(figure 4 to figure 5)**; wherein the actuator mechanism comprises a portion extending outside of the casing which portion is accessible to a user and which when the portion is moved by the user the movement brings the safety mechanism into its second configuration **(figure 4 to figure 5)**; wherein the safety mechanism in its first configuration prevents the trigger mechanism from moving **(0069)**; wherein the actuator mechanism has a structure selected from the group consisting of a button, a tongue and a lever **(figures 4 and 5 show a button)**; wherein the actuator mechanism is comprised of a component which applies a pulling force to the safety mechanism to pull the safety mechanism from its first configuration into its second configuration **(a pulling force is present as implied in figures 4 and 5 on the safety mechanism)**; further comprising: a retaining mechanism **(indentations/concave depressions on push rod 38)** which retains the safety mechanism of an enclosed injection device in its second configuration after the safety mechanism has been brought into its second configuration **(figures 4 and 5)**; wherein the safety mechanism comprises an obstracter portion which in the first configuration obstructs, and in the second configuration allows, movement of the trigger mechanism **(the balls of the ball latch act as obstructing mechanisms)**; wherein the safety mechanism comprises a collar shaped to surround a portion of the injection device, the collar is moveable from its first collar configuration into its second



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collar configuration in a direction generally perpendicular to a direction in which the medicament exits the orifice, the collar comprising an obstructer portion (**the balls of the ball latch act as a collar since they provide restraint**); wherein the trigger mechanism is comprised of two moveable upper (**46 touching trigger**) and lower sleeve (**49 touching trigger**) portions which on relative movement allow the drive mechanism to act, and the safety mechanism comprises an obstructer portion which in its first configuration obstructs, and in its second configuration allows, the relative movement of the sleeve portions (**figure 4 to figure 5**); a break-off tip (**22**) which closes the cartridge orifice prior to being broken off; wherein the casing provides for a sequential operation of the needleless injection device (**figure 4 to figure 5**); wherein the sequential operation provides for (a) breaking off the break-off tip; and (b) placing the safety mechanism in the second position (**figure 4 to figure 5**); wherein breaking off the break-off tip exposes an actuator for the safety mechanism (**allows for actuation thus exposing the actuator**); wherein the casing comprises moveable first (**46**) and second (**44**) casing components, a first casing component adapted to hold the injection device, and a second casing component adapted to bear upon the break-off tip as a result of relative motion of the first and second components to apply a force thereto causing the break-off tip to break off from an injection device enclosed within the casing (**figure 4 to figure 5**); wherein the first casing component is elongated with an opening at a first end (**figure 4**); wherein the first casing component is elongated along a longitudinal axis, and wherein the second casing component is designed to apply a rotary motion relative to the first portion so as to bear on the break-off tip of a container held by the first casing portion, and to apply a twisting shearing force to the frangible joint between the break-off tip and the container (**capability shown in figure 4**); wherein the

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rotary motion is chosen from: transverse to the longitudinal axis; perpendicular to the longitudinal axis; coaxial with the longitudinal axis; about a rotation axis parallel to but non-coaxial with the longitudinal axis; about a rotation axis at a non-zero angle to the longitudinal axis (**capability shown in figure 4**); wherein the rotary motion is about a rotation axis at a non-zero angle to the longitudinal axis (**capability shown in figure 4**); wherein the second casing component comprises a cover portion over the actuator for the safety mechanism which prevents operation of the actuator for the safety mechanism until the cover portion is removed (**figure 4 to figure 5**); wherein the actuator for the safety mechanism moves the safety mechanism from its first configuration to its second configuration (**figure 4 to figure 5**); wherein the drive mechanism comprises a compressed gas cylinder (**11**); wherein the casing comprises a first casing sub-part and a second casing sub-part which fit together by a method chosen from, a tight friction fit, and a snap-fit fit (**both appear to be shown in figure 4**); a first break away part (**outside of trigger, figure 4**) and a second break away part (**22**).

8. Claim 31 is rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,865,795 to Schiff et al.

Regarding claim 31, Schiff teaches a casing (**10**); a cartridge (**49**) containing a medicament and an orifice at one end; a drive mechanism (**12**) which upon actuation applies force to the medicament, forcing the medicament out of the orifice and through the patient's skin; a trigger mechanism (**18, 63**) which actuates the drive mechanism; a safety mechanism (**abstract; 16, 80, 106**) which, in a first configuration, prevents the trigger mechanism from actuating the drive mechanism and in a second configuration allows trigger mechanism to actuate the drive mechanism, wherein the casing encloses injector device components (**figure 4**)

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and incorporates an actuator mechanism **(38)** which moves the safety mechanism from its first configuration into its second configuration.

***Conclusion***

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Please refer to form PTO-892.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to GERALD LANDRY II whose telephone number is (571)270-7409. The examiner can normally be reached on M-F, 7:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/GEL/

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/Nicholas D Lucchesi/

Supervisory Patent Examiner, Art Unit 3763